

**NOROTIC EAR DROPS, SUSPENSION FOR DOGS**

**PRODUCT LITERATURE  
LABELLING AND PACKAGE LEAFLET**

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE>  
10ml/20ml/30ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NorOtic Ear Drops, Suspension for Dogs  
Marbofloxacin / Clotrimazole / Dexamethasone acetate

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 ml contains:  
3.0 mg Marbofloxacin  
10.0mg Clotrimazole  
0.9mg Dexamethasone (equivalent to 1.0mg dexamethasone acetate)

**3. PHARMACEUTICAL FORM**

Ear drops, suspension

**4. PACKAGE SIZE**

10ml/20ml/30ml

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Auricular use.  
Shake well for 1 minute before use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Not Applicable

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use

**10. EXPIRY DATE**

<EXP {month/year}>  
Once opened, use by:.....

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MA HOLDER**

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
Newry  
Co. Down, BT35 6JP  
Northern Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

<To be completed in accordance with national requirements>

**17. MANUFACTURER’S BATCH NUMBER**

<Batch><Lot> {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

10ml/20ml/30ml

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NorOtic Ear Drops, Suspension for Dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

1 ml contains:

3.0 mg Marbofloxacin

10.0mg Clotrimazole

0.9mg Dexamethasone (equivalent to 1.0mg dexamethasone acetate)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

10ml/20ml/30ml

**4. ROUTE(S) OF ADMINISTRATION**

Auricular use. Shake well before use  
Read the package leaflet.

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

<Batch><Lot> {number}

**7. EXPIRY DATE**

<EXP {month/year}>

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET**  
**NOROTIC EAR DROPS, SUSPENSION FOR DOGS**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
Newry  
Co. Down, BT35 6JP  
Northern Ireland

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NorOtic Ear Drops, Suspension for Dogs  
Canor vet (DK, FI)  
[Marbofloxacin/Clotrimazole/Dexamethasone Norbrook vet \(SE\)](#)

Marbofloxacin / Clotrimazole / Dexamethasone acetate

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

NorOtic Ear Drops Suspension for Dogs is a homogenous beige to yellow oily suspension containing 3.0 mg Marbofloxacin, 10.0mg Clotrimazole, 0.9mg Dexamethasone (equivalent to 1.0mg dexamethasone acetate) and 1.0mg Propyl Gallate (E310) per ml.

The product also contains Sorbitan Oleate, Silica Hydrophobic Colloidal and Triglycerides Medium-Chain.

**4. INDICATION(S)**

Treatment of otitis externa of both bacterial and fungal origin - respectively due to bacteria sensitive to marbofloxacin, and fungi especially *Malassezia pachydermatis* sensitive to clotrimazole.

The product should be used based on susceptibility testing of isolated bacteria.

**5. CONTRAINDICATIONS**

Do not use in dogs suffering from perforation of the tympanic membrane.  
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

## **6. ADVERSE REACTIONS**

Usual adverse reactions associated with corticosteroid drugs may be observed (changes in biochemical and haematological parameters, such as increase of alkaline phosphatase, and of aminotransferase, some limited neutrophilia).

Prolonged and intensive use of topical corticosteroid preparations is known to trigger local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed wound healing.

On rare occasions, the use of this product may be associated with deafness, mainly in elderly dogs and mostly of a transient nature.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Auricular use.

One drop of the preparation contains 71µg marbofloxacin, 237µg clotrimazole and 23.7µg dexamethasone acetate.

Apply ten drops into the ear once daily for 7 to 14 days.

After 7 days of treatment, the veterinary surgeon should evaluate the necessity to extend the treatment another week.

When the product is intended for use in several dogs, use one cannula per dog.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Shake well for 1 minute before use.

After application, the base of the ear may be massaged briefly and gently to allow the preparation to penetrate to the lower part of the ear canal.

## 10. WITHDRAWAL PERIOD

Not Applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30°C

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after "EXP".

Shelf life after first opening the container: 3 months.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

## 12. SPECIAL WARNING(S)

### Special precautions for use in animals:

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antibiotics.

Before treating with the product, the integrity of the tympanic membrane must be verified.

Official and local antimicrobial policies should be taken into account when the product is used.

The external ear canal should be meticulously cleaned and dried before treatment.

Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.

Quinolone class drugs have been associated with cartilage erosions in weight-bearing joints and other forms of arthropathy in immature animals of various species. The use of the product in young animals is not recommended..

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands carefully after applying the product.

Avoid contact with eyes. In the event of accidental eye contact, rinse with clean water.



People with known hypersensitivity to fluoro(quinolones) and other compounds in the product should avoid contact with the veterinary medicinal product.

Use during pregnancy, lactation:

Do not administer to pregnant or lactating bitches.

Overdose (symptoms, emergency procedures, antidotes), if necessary:

Changes in biochemical and haematological parameters (such as increase of alkaline phosphatase, aminotransferase, some limited neutrophilia, eosinopenia, lymphopenia) are observed with three fold the recommended dosage; such changes are not serious and will reverse once the treatment has stopped.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

Packaging Quantities:

Available in vials of 10ml, 20ml and 30ml

Not all pack sizes may be marketed

Marbofloxacin is a synthetic bactericidal agent belonging to the fluoroquinolone family that acts by inhibiting DNA gyrase. It exhibits a broad spectrum of activity against Gram-positive bacteria (e.g. *Staphylococcus intermedius*) and against Gram-negative organisms (*Pseudomonas aeruginosa*, *Escherichia coli* and *Proteus mirabilis*).

Clotrimazole is an anti-fungal agent that belongs to the imidazole family and which acts by causing changes in membrane permeability, allowing intracellular compounds to leak from the cell and thus inhibiting cellular molecular synthesis. It exhibits a wide spectrum of activity and is aimed, in particular, at *Malassezia pachydermatis*.

Dexamethasone acetate is a synthetic glucocorticoid exhibiting anti-inflammatory and anti-pruritic activity.

Distributor:

<To be completed in accordance with national requirements>